REMARKS

Applicant sincerely appreciates the very detailed examination evidenced by the Official Action mailed February 8, 2006 (hereinafter "the Official Action"). In response, Applicant hereby affirms the provisional election of Group II, including Claims 19-36, 55-72, and 91-107 for examination. Applicant has further canceled the claims drawn to invention I. Applicant has also made several amendments to the claims as suggested by the Examiner to address the objections thereto as well as the rejections under Section 112.

With regard to the rejections, Applicant has amended the pending independent claims to further clarify patentable distinctions between these claims and the cited references. For example, the independent claims have been amended to further clarify that an electric stimulus is applied to a region of the heart "determined to contain a fast activating region." *Amended Independent Claim 19.* Applicant has also amended several of the dependent claims to be in independent form to highlight the recitations therein for further examination. Accordingly, Applicant respectfully requests the withdrawal of all rejections and the allowance of all claims for at least the reasons described herein.

Applicant Affirms The Provisional Election.

Applicant affirms the provisional election of the claims included in Group II as specified by the Examiner in a telephone conversation on January 23, 2006. *Official Action, page 3.* Applicant has also canceled Claims 1-18, 37-54, and 73-90 as being drawn to a nonelected invention as required by the Examiner.

The Objections To The Claims Have Been Overcome By Amendment.

Claims 24, 30-32, 59, 65, 95, and 101 stand objected to over several typographical errors therein. *Official Action, page* 3. Applicant sincerely appreciates the Examiner's diligence in highlighting the errors in these claims and the Examiner's suggestions regarding corrections thereto. In response, Applicant has amended each of the above-recited claims as specifically suggested by the Examiner. Accordingly, the objections to the above-cited claims have been overcome by amendment.

Claim 62 also stands objected to over what appears to be an erroneous recitation of "during fibrillation" in the third line thereof. In response, Applicant has amended Claim 62 to remove this erroneous recitation as suggested by the Examiner. Accordingly, the objection to Claim 62 has also been overcome by amendment and should be withdrawn.

The Rejections Based On Section 112 Have Been Overcome By Amendment.

Claims 23, 29, 58, 64, 94, and 100 stand rejected under 35 U.S.C.§ 112, second paragraph. *Official Action, page 4*. Specifically, the Official Action has highlighted potential confusion over the recitation of "first wavefront" in the above-cited claims. In response, Applicant notes that the Examiner has examined the pending claims based on the assumption that the recited "first wavefront" comprises a "mother rotor." In response, Applicant has amended each of these claims to specifically recite that the first wavefront comprises a mother rotor as assumed by the Examiner. Accordingly, the rejections of these claims under Section 112, second paragraph have been overcome by amendment and should be withdrawn.

The Amended Independent Claims Are Patentable Over The Cited References.

Claims 19-20, 27, 55, and 62 stand rejected under 35 U.S.C. § 102 over both U.S. Patent No. 5,107,834 to Ideker et al. ("Ideker '834") and U.S. Patent No. 5,224,476 to Ideker et al. ("Ideker '476"). *Official Action, page 5, and 7*. Although Applicant maintains that the subject matter of the present claims is distinguishable from the material included in both Ideker '834 and Ideker '476, Applicant has further amended independent Claims 19, 27, 55, 62, 91 and 98 to further clarify that the fastest activating region of the heart is "determined." For example, independent Claim 19 has been amended to recite in part:

> detecting a premature contraction of the heart for a plurality of heart beats characterized by nonsustained tachycardia; and **applying an electric stimulus to a region of the heart determined to contain a fastest activating region**.

As demonstrated by the above-highlighted recitation, the cited references do not disclose, or suggest, at least "applying an electric stimulus to a region of the heart

determined to contain a fastest activating region." It is Applicant's understanding that the Examiner contends that because the approaches in Ideker '476 and Ideker '834 apply electric stimulus to the entire heart, then by default, the stimulus is also applied to the fastest activating region contained therein. Applicant understands the position taken by the Examiner and has, therefore, further amended the claims to highlight that the fastest activating region is "determined" and, therefore, is not disclosed by Ideker '476 or Ideker '834.[1]

As noted above, notwithstanding the amendments made to the independent claims, the present subject matter is distinguishable from both Ideker '476 and Ideker '834 as these references do not identify any particular region of the heart as being particularly important. To the contrary, both of these references apply electric stimulus **to the entire heart** and, therefore, do not disclose applying electric stimulus to the fastest activating region as described in Applicant's disclosure. For example, in some embodiments according to the invention, the electric stimulus can be about 100 volts, which is significantly less than the stimulus discussed in Ideker '476 and Ideker '834 so that the electric stimulus applied in these embodiments substantially affects only the fastest activating region. See, for example, Application at page 10, line 33-page 11, line 1, wherein Applicant describes the different voltages that can be applied to the fastest activating region.

Furthermore, Applicant's disclosure also describes how the electric stimulus is applied proximate to the fastest activating region so as to have the desired affect (i.e., interruption of the mother rotor present in the fastest activating region). See, for example, Application at page 7, lines 30-34, which evidences that the electric stimulus in embodiments according to the invention affects substantially only the fastest activating region, not the entire heart. Accordingly, it is Applicant's position that the present subject matter is distinguishable from both Ideker '476 and Ideker '834 for at least these additional reasons.

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[1] Applicant notes that the rejections of Claims 21, 31-36, 56, and 68-72 under Section 103 over Ideker '476 and Ideker '834 both appear to admit that these references to not disclose locating the fastest activating region. *Official Action, page 10 and 11.* Accordingly, Applicant submits that Ideker '476 and Ideker '834 clearly do not disclose the recitations of the amended independent claims.

Applicant also maintains that Ideker '476 and Ideker '834 cannot be fairly used to make out a *prima facie* case of obviousness against the amended independent claims recited above. In particular, to establish a *prima facie* case of obviousness, three basic criteria must be met. The prior art reference (or references when combined) must teach or suggest all the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, and there must be a reasonable expectation of success of the combination. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. See MPEP § 2143. As stated by the Court of Appeals for the Federal Circuit, to support combining references in a § 103 rejection, evidence of a suggestion, teaching, or motivation to combine must be clear and particular, and this requirement is not met by merely offering broad, conclusory statements about teachings of references. *In re Dembiczak*, 50 USPQ2.d 1614, 1617 (Fed. Cir. 1999).

As described above in reference to the rejections under Section 102, Ideker '476 and Ideker '834 both treat all portions of the heart to be the same, and therefore do not disclose determining a fastest activating region of the heart. For example, Ideker '834 reads:

> It is the desire to defibrillate the heart by creating a voltage gradient throughout substantially all of the heart which is above a critical voltage gradient while delivering a minimum energy shock. *Ideker '834, Column 2, lines 27-31.*

Ideker '834 goes on to read:

> Unlike the prior systems which attempt to achieve uniform voltage gradients through spatial summation of shocks, the present invention accepts non-uniformity and uses it as an advantage to defibrillate the heart with an overall lower energy. **Thus, substantially the entire myocardium is depolarized by a voltage gradient above the critical voltage gradient, but with the total shock strength of the first and second shocks being substantially reduced.** *Ideker '834, Column 2, lines 60-68.* [emphasis added]

Therefore, as demonstrated by the discussion in the "Summary of the Invention" of Ideker '834, the approach discussed therein does not distinguish

between different parts of the heart , and specifically, does not determine the fastest activating region. Moreover, there is no motivation to modify Ideker '834 to include a determination of the fastest activating region as Ideker '834 does not have a need to distinguish between different portions of the heart as it is the stated intention therein to apply the electric stimulus to the entire myocardium. Accordingly, there is no motivation in Ideker '834 to determine a fastest activating region as the discussion therein treats all portions of the heart the same and, moreover, does not even mention a fastest activating region.

Ideker '476 also does not disclose or suggest "applying an electric stimulus to a region of the heart determined to contain a fastest activating region" as Ideker '476 focuses on how to apply defibrillation stimulus to minimize energy requirements to reduce the size of the equipment used to provide the stimulus and to reduce damage to tissue adjacent to implanted electrodes. *See, for example, Column 2, lines 47-55 of Ideker '476.* Accordingly, Ideker '476 addresses the problem of the size of the equipment used to defibrillate the heart and how to deliver adequate electrical stimulus to the entire heart while reducing the potential for damage to tissue adjacent to the electrodes. However, Ideker '476 does not suggest applying an electrical stimulus to a region of the heart determined to contain a fastest activating region as there is no discussion in Ideker '476 that hints at why one particular area of the heart (*i.e.*, the fastest activating region) is more important than any other.

Applicant further notes that it appears that the Official Action is placing the burden of establishing nonobviousness on the Applicant by asserting:

> It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method and system as taught by Ideker '476 with such ways to locate the fastest activating region, because Applicant has not disclosed that such a localizing method provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the mapping technique for electrode configuration and /or placement as taught by Ideker '834 ,because it provides preferable electrode placement for the best defibrillation of the myocardium and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Ideker '834. *Official Action, pages 10-11.*

As understood by Applicant, the above-cited passage of the Official Action suggests that it is the Applicant's duty to provide an advantage, a useful and particular purpose, or a solution to a stated problem in order to overcome what essentially appears to be a presumption of obviousness. Respectfully, the burden is actually placed upon the Office to establish a *prima facie* case of obviousness including providing clear and particular evidence of a motivation or suggestion to modify (either Ideker '834 or Ideker '476) to provide the present claimed subject matter. In fact, the reasoning set out in the Official Action under the rejections based on Section 103 appear to be conclusory in nature and include the type of reasoning that is generally forbidden by the caselaw outlined above.

Furthermore, the Official Action appears to conclude the allegation of obviousness with a statement indicating that the elements admitted to be missing from Ideker '834 and Ideker '476 would be obvious design choices:

> Therefore, it would have been an obvious matter of design choice to modify Ideker '834 to obtain the invention as specified in the claims. *Official Action, page 11.*

> Therefore, it would have been an obvious matter of design choice to modify Ideker '476 to obtain the invention as specified in the claims. *Official Action, page 11.*

Respectfully, the Official Action has provided no authority as to how an element which is not disclosed or suggested in the cited reference (either Ideker '834 or Ideker '476) can be fairly characterized as a mere design choice when the element is not itself disclosed or suggested. In other words, according to Applicant's understanding, a design choice is selecting a parameter of a disclosed or suggested element (such as a length for a disclosed screw), and not for the inclusion of an element that is otherwise not mentioned. For example, Applicant submits that it would not be a design choice to determine a fastest activating region when there is no discussion of making any such determination. Accordingly, Applicant respectfully submits that the conclusion that the recitations at issue would be a design choice in either Ideker '834 or Ideker '476 is incorrect as there is no disclosure or suggestion in either of these references of determining the fastest activating region or even an acknowledgement of the existence of a fastest activating region.

In view of the above, Applicant respectfully maintains that none of the cited references, either singularly or in combination, discloses or suggests the amended recitations of independent Claims 19, 27, 55, 62, 91, and 98. Furthermore, the claims which depend from each of the above-listed independent claims is also patentable at least per the patentability of the respective amended independent claim.

Notwithstanding Applicant's assertion that there is no burden on the Applicant to provide advantages, etc. of the present invention, Applicant's disclosure does in fact provide some of the material that the Official Action alleges to be missing. For example, the application reads in-part:

> Embodiments according to the present invention may be used to interrupt, or reduce the likelihood of, fibrillation in hearts by, for example, applying electrical stimuli to a region of the heart that contains what is sometimes referred to as the "mother rotor." Applying electrical stimuli to the region of the heart containing the fastest activating region may cause the "mother rotor" to halt, thereby interrupting fibrillation of the heart. Alternatively, in some embodiments according to the present invention, applying the electrical stimuli to a region that is likely to include the mother rotor during fibrillation may reduce the likelihood that fibrillation may occur in the heart. As used herein, the term fibrillation can include both atrial fibrillation as well as ventricular fibrillation. *Present Patent Application, page 5, lines 5-14.*

As shown by the exemplary passage of the present application, one of the advantages described in Applicant's disclosure is that by applying an electric stimulus to the determined fastest activating region, it is more likely that the mother rotor can be halted to interrupt defibrillation of the heart. Accordingly, contrary to assertions of the Official Action, Applicant's disclosure does in fact provide discussion of the damages, etc. provided by embodiments according to the present invention.

Many Of The Other Claims Are Also Patentable.

In addition to the reasons discussed above in reference to the amended independent claims, Applicant maintains that many of the other claims are also patentable for additional reasons. For example, Claims 21, 36, 56, 72, and 107 have been redrafted in independent form to recite, for example:

> detecting a premature contraction of the heart for a plurality of heart beats characterized by nonsustained tachycardia; applying an electric stimulus to a region of the heart that is likely to contain a fastest activating region, wherein a location of the fastest activating region is determined by: **inducing fibrillation of the heart; and determining at least one of a monophasic activation potential (MAP) reading associated with the fibrillating heart, a refractory period associated with the heart using premature stimulation, and a power spectrum analysis to provide a spectrum with a peak power at a highest frequency.**
> *Independent Claim 21*

Applicant notes that these recitations include some similarity to the recitations added to the amended independent claims described above. Similarly, the rationale provided for the rejection of these claims is insufficient. In particular, the Official Action admits that there is no express disclosure in either Ideker '476 or Ideker '834 of the recitations emphasized above, but goes on to conclude that it would have been an obvious design choice to modify a respective reference to disclose these recitations. Applicant respectfully maintains, however, that neither Ideker '476 or Ideker '834 includes any discussion or suggestion of inducing fibrillation or of providing a MAP reading associated with the fibrillated heart, a refractory period associated with the heart using premature stimulation, or a power spectrum analysis to provide a spectrum with a peak power at highest frequency. There is simply no discussion or suggestion in either of these references of any of the specific determinations recited in the claims cited above. Accordingly, it can hardly be said that it would be an obvious design choice to modify a reference to include such specific recitations, as well as recitations that are not even hinted at in the cited references. Accordingly, Applicant respectfully maintains that independent Claims 21, 36, 56, 72 and 107 are also patentable for at least these additional reasons.

CONCLUSION

Applicant has amended the claims to address the objections and rejections of the claims under Section 112 as suggested by the Examiner. Applicant has also amended the independent claims to further clarify that a fastest activating region is determined in contrast to the cited references, and, further, there is no clear and

particular evidence of a motivation or suggestion to modify the cited references or a determination of a fastest activating region. Accordingly, Applicant respectfully submits that the pending claims are in condition for allowance which is respectfully requested in due course. If any informal matters should arise, the Examiner is encouraged to contact the undersigned by telephone at (919) 854-1400.

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